REMARKS

The present invention relates to an agent for a clinical laboratory test.

In the Office Action dated august 12, 2003, claims 13-24 were rejected.

Regarding priority, at page 2 of the Office Action, the Examiner indicated that reference should be made to the "prior" PCT application and foreign priority document. Furthermore, at page 3 of the Office Action, the Examiner indicated that a substitute specification in proper idiomatic English and in compliance with 37 C.F.R. § 1.52(a) and (b) is required. Including the correction of the term "hem" to --heme--. Still further in this regard, the Examiner has required revision of the Abstract of the Disclosure.

In accordance with the Examiner's requirement, a substitute specification is attached hereto including a clean version thereof and a version showing the changes made by strike through or double bracketing with respect to deletions and underlining with respect to insertions. Included in the changes is a sentence as proposed by the Examiner (except correcting the final date) at the beginning of the specification regarding priority, although Applicants respectfully submit that such a statement is not required. Similarly, the Abstract has been amended responsive to the Examiner's suggestions.

Turning to the claims, the Examiner objected to claims 15 and 16 with respect to the wording including the use of proper chemical nomenclature.

Furthermore, at pages 5-6 of the Office Action, the Examiner raise several issues with respect to claim 17-22 under 35 U.S.C. § 112, second paragraph. Still further regarding the claims, claims 13-22 were rejected under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. §

103(a) based on U.S. Patent 5,895,810 (Light et al). Furthermore, claims 23-24 were rejected under 35 U.S.C. § 103(a) based on Light et al in view of U.S. Patent 5,686,316 (Fiechtner et al) in light of U.S. Patent 6,124,134 (Stark).

In response to the objections and rejections of the claims, the claims have been extensively amended herein above, including the cancellation of claims 16, 18, 20, 22, and 24, the amendment of claims 13-15, 17, 19, 21, and 23, and the addition of new claims 25-38.

In view of the various amendments to the claims, it is respectfully submit that the objections and rejection under 35 U.S.C. § 112, second paragraph have been obviated. Accordingly, withdrawal of the 35 U.S.C. §112 rejections is respectfully submitted to be proper.

With respect to the prior art rejections, Applicants respectfully submit that the amended claims are unanticipated and nonobvious in view of the cited prior art. Further in that regard, the Examiner is respectfully requested to consider the specific comments below.

Light et al. U.S. Patent 5,895,810

Light et al relates to a method for preparation of resistant hemoglobin and methohemoglobin useful for treating ahemia or as a blood substitutue. A method for stabilizing hemoglobin with SH compound, including D.L-cystein, is disclosed. However, an agent for a clinical laboratory test is not disclosed, and a chelating agent or a saccharide is not used therein as a constitutive element.

Stark (U.S. Patent 6,124,134)

Stark describes an apparatus and method for determining either stable or unstable glycated compound in blood.

An agent for clinical laboratory test is not disclosed, nor is an SH compound, a chelating agent or a saccharide disclosed as a constitutive element.

Fiechtner et al. (U.S. Patent 5,686,316)

Fiechtner et al discloses a A method for preparing a glycated hemoglobin for use as a standard compound in an assay, and said standard compound.

An agent for a clinical laboratory test is not disclosed, and neither a stabilizing hemoglobin compound, a chelating agent, nor a saccharide is used as a constitutive element.

As is clear above, the cited references neither disclose nor suggest the presently claimed invention.

In considering the Light et al, in which hemoglobin composition is disclosed as a blood substitute, the required composition is different from the agent for clinical test (the presently claimed invention).

Thus, stabilization of the hemoglobin is not a sufficient required condition for use as an agent. The influence of a false positive reaction due to a contaminant in the measurement should be considered. It is disclosed that cystein, etc., are effective for stabilizing Hb, when it is used as a blood substitute. However, a chelating agent or a saccharide is also required together as indispensable ingredient when it is used as the agent for the clinical test. Without addition of

such additives, accurate measurement of the Hb can not be obtained. Please note that according to the present invention, addition of a chelating agent or a saccharide is required together with cystein, etc.

The descriptions of Stark and Fiechtner et al relate to a relation between glycohemoglobin and hemoglobin in blood. Regardless of the description of G-Hb's agent in the Fiechtner et al reference, how to stabilize Hb is not disclosed at all.

In summary, the Light et al and Stark references are different from the present invention in their object and constitution of the composition, and Fiechtner et al reference is also different in its constitution of composition, and does not teach a way of stabilizing Hb at all. Accordingly, there is no motivation for combining the contents of Light et al with those of Stark and Fiechtner et al by those skilled in the art.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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